Supreme Court, U.S.
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No. 01-911

IN THE

Supreme Court of the United States

ASHOK TANKHA,

Petitioners,

v.

WYETH-AYERST LABORATORIES, INC., A DIVISION OF AMERICAN HOME PRODUCTS CORPORATION AND FRED HASSAN, PRESIDENT OF WYETH-AYERST LABORATORIES, INC. AND MARSAM PHARMACEUTICALS, INC. AND MARVIN SAMSON, PRESIDENT OF MARSAM PHARMACEUTICALS, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF PENNSYLVANIA

RESPONDENTS' BRIEF IN OPPOSITION

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COUNTER-STATEMENT OF THE CASE

The trial court found that Petitioner made a calculated decision to breach his contractual and common law duties to his employer, Wyeth, by attempting unlawfully to exploit trade secret information entrusted to him relating to its one-of-a-kind product, Premarin. Having conclusively demonstrated Petitioner's intent to employ its trade secrets in his own enterprise, Wyeth was entitled to a remedial injunction tailored to protect its legitimate interests. Petitioner raises no issue of constitutional dimension or patent law that warrants further review of the judgments of the trial court and two appellate courts rejecting his claims and protecting Wyeth against his further unlawful conduct. The scope of the trial court's injunction, necessitated by the gravity of Petitioner's misconduct and the threat he poses to Wyeth's trade secrets, simply does not disrupt the balance struck by this Court between federal patent and state trade secret laws.

A thorough and accurate recitation of the facts is important to this Court's understanding of the context in which the trial court fashioned its decree. The summary that follows is principally based on the trial court's detailed, thorough and unchallenged findings of fact.

A. The Premarin Manufacturing Process Is A Wyeth Trade Secret

Wyeth is the manufacturer of Premarin, a drug used to treat menopausal symptoms and prevent osteoporosis. It is one of today's most-prescribed pharmaceuticals, generating over a billion dollars in annual sales. App. at 10a, ¶1; 11a, ¶4. Premarin's seventeen active ingredients, conjugated estrogens, are extracted from hormones found in the urine of pregnant horses (pregnant mares' urine or "PMU"). App. at 10a, ¶1.

Premarin is not an "off-patent" drug. Wyeth manufactures Premarin using a secret, proprietary process developed and protected from disclosure over the course of more than 50 years. App. at 10a, ¶2. Although expired patents from the 1940's and 50's discuss various laboratory methods of PMU extraction, none reveals

Wyeth's production steps for extraction, or the other 90 percent of the Premarin manufacturing process. *Id.*

The secret, proprietary nature of Wyeth's Premarin manufacturing process is reflected in the marketplace. By contrast with every other "off-patent," top-selling drug such as Tagamet or Valium, not a single FDA-approved generic substitute for Premarin exists, despite the expiration long ago of the patents cited by Petitioner. App. at 11a, ¶4.

It is impossible for a Wyeth outsider to know whether Wyeth actually used the 1947 and 1952 patents, or any others, in its process for manufacturing Premarin. App. at 21a, ¶45. Wyeth's expert, Dr. Michael Dey, testified, and the Court found, that, in any event, the patents cited by Petitioner do not in fact disclose any part of Wyeth's manufacturing process. *Id.*

B. Petitioner Acquires Knowledge Of Wyeth's Trade Secrets

In March 1989, Wyeth hired Petitioner, a chemical engineer (and a licensed patent lawyer), as a "process project engineer" in its engineering group in Radnor, Pennsylvania. App. at 12a, ¶6. Petitioner had no prior experience related to any conjugated estrogens product. App. at 14a, ¶11. Petitioner signed two employment agreements prohibiting competition with Wyeth during employment, and disclosure or use during employment "and thereafter" of "any of the Company's confidential business information and trade secrets, such as . . . processes." App. at –, ^^, , .

Relying on these agreements and Petitioner's trust, Wyeth afforded him access to both Premarin manufacturing process information and the facilities where the Premarin manufacturing steps were performed. Petitioner admitted that all the Premarin manufacturing information he received was confidential and proprietary and should not be disclosed to outsiders. App. at 15a, ¶16. Petitioner also admitted that he learned Wyeth's proprietary, confidential and trade secret process for manufacturing Premarin during his employment. App. at 14a, 15a, ¶¶12, 16.

C. Petitioner's Attempts To Exploit Wyeth's Trade Secrets

Less than two years after being hired, and while still a Wyeth employee, Petitioner devised a plan to launch his own company to manufacture a generic version of Premarin. App. at 15a, ¶17. Petitioner's plan was never to make some unspecified estrogens product using, as he claimed, information "from the expired patent," "public domain information," or his "scientific and engineering education and skill." On the contrary, every step Petitioner took to advance his plan left behind a footprint of his intent to use Wyeth's confidential information to duplicate Premarin.

Petitioner's approach to Marvin Samson, president of generic drug manufacturer Marsam Pharmaceuticals, revealed his intent to directly trade on Wyeth's trade secrets. Samson testified that Petitioner offered him those secrets when proposing that Marsam enter into a venture to manufacture generic Premarin using Wyeth's information. Samson was so offended by the impropriety of Petitioner's proposal that he ended the meeting, and reported Petitioner's activities to Wyeth. App. at 16a, 17a, ¶¶20-23.

Wyeth's subsequent investigation confirmed Petitioner's unlawful intent. Petitioner admitted in an interview with Wyeth's security chief that he had begun plans to produce a generic form of Premarin, and that he had met with Samson to further those plans. App. at 17a, ¶24. Petitioner further admitted at trial that he had told a supervisor and friend that he had indeed offered information on Wyeth's Premarin process to a competitor. App. at 17a, ¶25.

Wyeth's security found more direct evidence of Petitioner's *mala fides*. It found three sets of highly confidential Premarin process documents in a search of a file cabinet drawer in Petitioner's office. App. at 17a, ¶26. These documents contained detailed trade secret production information of various portions of the Premarin manufacturing process performed at two of Wyeth's facilities. *Id.* Petitioner had no job-related, or other legitimate reason, to have them in his office. App. at 19a, ¶33. Petitioner never denied that the documents found in his office belonged to him. App. at 18a, ¶28.

Not surprisingly, Wyeth concluded based on the information from Samson and its investigation that Petitioner had in fact offered its trade secret information to its competitor. Accordingly, Wyeth fired him.

Prompted by the incident and the danger it presented to the welfare of the company, Wyeth's President, Fred Hassan, sent its management-level employees a memorandum advising that "we recently learned that a trade secret for one of our main products was offered to a generic competitor" and asking employees to be vigilant in protecting its intellectual property. The memorandum did not identify Petitioner or the product or state the action taken in response to the incident. R. 347a (Memorandum).[1]

D. Commencement Of This Action Did Not Deter Petitioner From Continuing His Efforts To Trade On Wyeth's Trade Secrets.

Several months later, Petitioner filed this action against Wyeth, its President, Fred Hassan, Marsam and Marvin Samson asserting, *inter alia*, claims for defamation and tortious interference with business relations, focusing on the alleged effect of the memorandum.[2] App. 37a. Wyeth filed a counterclaim, seeking a permanent injunction to prevent Petitioner's use of the confidential, proprietary and trade secret information learned during his employment. App. 9a.

Petitioner's efforts to capitalize on the knowledge he acquired at Wyeth did not stop with his firing or the commencement of his lawsuit. He formed various shell companies dedicated to purifying conjugated estrogens and continued to solicit investors. App. 19a, ¶35. Again, Petitioner's plans relating to these efforts explicitly showed he did not intend to use expired patents to make a "generic conjugated estrogen product," but instead intended to use Wyeth's

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1 "R" refers to the record before the Supreme Court of Pennsylvania.

2 At trial on his claims, Petitioner agreed to a non-suit on all of his claims against Marsam and Samson. Petitioner also voluntarily dismissed all claims against Wyeth and Hassan except the claim for defamation. App. 38a. The jury returned a verdict for those defendants, finding that Petitioner had not been defamed by the memorandum he alleged accused him of the theft of trade secrets and industrial espionage. *Id.*

proprietary information and Wyeth's process to duplicate Premarin. Petitioner addressed the distinction himself in a discussion with a potential finance agent. He specifically told the agent the reason he could make generic Premarin, when no other company had been able to do so, was that the drug was so difficult to make, and that the problem related to understanding the "process," *not* the "patent." App. at 20a, ¶41.

Most telling of all, was Petitioner's activities with potential investor Gufic Ltd. They showed he intended to produce an exact, generic equivalent of the FDA-approved drug, Premarin, *using Wyeth's process*. Petitioner testified at trial that he would never tell anyone he would manufacture a generic version of Premarin using the same process used in the manufacture of Premarin because it would be "unlawful" and "wrong," and would breach his contractual obligations to Wyeth. R. 231a-232a (Testimony of Ashok Tankha). Petitioner, confronted with his own letter, was then forced to admit he had done precisely what he said he would not and could not legally do.

Petitioner's letter was occasioned by Gufic asking him how he proposed to manufacture a generic equivalent of Premarin. Petitioner responded by letter to assure Gufic that his generic version of Premarin would be approved by the FDA, but he did not say he would rely on a patent or patents to make the product. R. 370a-372a (Letter to Gufic); 235a-237a (Testimony of Ashok Tankha). Instead, he boasted in a letter that he never expected to see the light of day:

> [T]he product [my company] will manufacture in 1994, will be identical to Premarin, *using the identical process* and identical raw materials used in the manufacture of Premarin.

App. 20a, ¶39 (emphasis added).

Based on these findings, the trial court concluded that there was a strong likelihood that Petitioner would unlawfully use Wyeth's trade secrets and that he posed a grave threat to the confidential and proprietary information he acquired at Wyeth. App. 23a, ¶57; 25a. ¶8. Accordingly, the Court found that an injunction prohibiting Petitioner from engaging in the business of production

of conjugated estrogens was necessary to protect Wyeth's interests in its trade secrets. App. 46a. Based on the record, the Court also concluded that the injunction posed no obstacle to Petitioner's pursuit of his livelihood. Indeed, the Court found no evidence that Petitioner would suffer any harm from the injunction at all. App. 47a, 48a.

REASONS TO DENY THE PETITION

A. The Petition Contains Misstatements Of The Record That Undermine Petitioner's Argument For A Writ

1. Premarin Is Not An Off-Patent Drug

The fundamental factual premise of Petitioner's argument for a writ is echoed repeatedly throughout his Petition: (1) "...Wyeth once held patents for conjugated estrogens (trade name 'Premarin')" Pet. at 7; (2) "In the 1940's and 1950's. . .Wyeth obtained patents for the manufacture of conjugated estrogens (trade name 'Premarin')" Pet. at 7; (3) "The evidence at trial showed that in the late 1940's and early 1950's Wyeth obtained patents for making conjugated estrogens marketed under the brand name Premarin." Pet. at 4. From this foundation, the argument proceeds to raise an alleged conflict between: (a) the Patent Act's dedication of the disclosures in the so-called "Premarin Patents" to the public; and (b) the scope of the trial judge's injunction necessary to protect Wyeth's trade secrets against further unlawful exploitation by Petitioner. In that regard, reference is made to the state court's ruling that purportedly "afforded Wyeth all of the *benefits* of the patent bargain Wyeth struck with the public under federal law when it enjoyed a patent monopoly for its once fledgling product." Pet. at 12 (emphasis in original).

Petitioner's entire argument is constructed on this non-existent foundation — the fiction that Wyeth's Premarin manufacturing process was once fully disclosed in patents.[3]

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3 Petitioner's second question presented for review rests squarely, indeed entirely, on this false premise. This question also provides no basis for granting the Petition because: (1) the premise is wholly unsupported by the record; (2) there was no objection to the questioned testimony at trial; (3) the question was not

The trial court found the exact opposite to be true in its second finding of fact:

> The Court finds: ... that Wyeth manufactures Premarin using a proprietary and secret formula or process that it and its predecessor companies have developed over the course of more than fifty (50) years; that although several expired patents dated in the 1940's and 1950's set forth various methods of extracting estrogens from PMU, none identifies the process Wyeth uses to perform either its extraction functions or the hundreds of other steps that comprise the remaining ninety (90%) percent of Wyeth's Premarin manufacturing process; and that although the patents set forth a method of obtaining a substance containing estrogens, none identifies a process for duplicating Premarin, or even any part of Wyeth's Premarin manufacturing process.

App. 10a,¶2.

The Court also found:

> . . .that clearly, all information about the Premarin process was not disclosed in the expired patents, and that Plaintiffs testimony to the contrary was not credible.

App. 21a ¶44.

> . . .Dr. Dey [was] credible when he testified that the 1947 and 1952 patents, in fact, do not disclose any part of Wyeth's process for making Premarin.

App. 21a ¶46

In short, the evidence at trial completely debunked Petitioner's claim that Premarin is an "off-patent" drug. It unequivocally established that Wyeth's manufacturing processes for Premarin, from urine collection and conjugated estrogens extraction through purification, blending and tableting was never disclosed in any

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raised and preserved in the state court appeal (See App. at 6a-8a.); and (4) the argument in support of it in the Petition is nearly nonexistent, falling far short of this Court's requirement of a "direct and concise argument amplifying the reasons relied on for allowance of the writ." Supreme Court Rule 14.1(h).

patent, nor was there any obligation to do so. App. 21a. ¶45. Thus, although certain patents taught different methods to extract estrogens on a laboratory scale, none identified a process for duplicating Premarin or any part of Wyeth's complex manufacturing process. *Id.*

Petitioner's argument that the Premarin manufacturing process, as purported to be revealed in patents, is in the public domain is completely contradicted by the record. Therefore, the argument that a state court cannot enjoin Petitioner from making conjugated estrogens using Wyeth's process, because that process has already been dedicated to the public, is without merit and raises no issue of federal law.

2. Patent Law Did Not Require Wyeth To Disclose Its Proprietary Manufacturing Process

Petitioner tries to avoid the settled findings of the trial court and independently establish a factual predicate for his argument by urging that the patents must have disclosed the entire process for the manufacture of Premarin because that is what the patent law requires. Pet. at 7. This interpretation of the law is simply wrong.

Patent law does not prevent the patent holder from improving on, or changing, a process disclosed in a patent. It also does not require the patentee of a process to disclose the means of mass producing a product or producing it in the most cost-efficient way. Additionally the law allows a company to obtain patent protection for only a fraction of an entire process, and retain the balance of the manufacturing processes as trade secrets. *See Christianson v. Colt Indus. Operating Corp.*, 870 F.2d 1292, 1303 (7th Cir.) (the scope of an invention can exceed the claim made and disclosed in the patent), *cert. denied*, 493 U.S. 822 (1989); *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544 (Fed. Cir. 1987) ("Patents are not production documents, and nothing in the patent law requires that a patentee must disclose data on how to mass-produce the invented product..."), *vacated on other grounds*, 486 U.S. 800 (1988) (vacated on jurisdictional grounds and remanded to Seventh Circuit which substantially adopted the Federal Circuit's reasoning); *Richardson v. Suzuki Motor Co.*, 868 F. 2d 1226 (Fed. Cir.), *cert. denied*, 493 U.S. 853 (1989) (rejecting argument that

information developed after the issuance of a patent was barred from trade secret status because it was generally disclosed in the patent, or known to the general public or because it merely implemented the patented invention).

As a consequence, Wyeth's continued improvements to its extraction process over more than 50 years, the design and maintenance of its large scale production facilities and mass manufacturing steps, as well as its processes related to collection, purification blending and tableting of Premarin have, quite properly, never been the subject of patents. Instead, Wyeth elected to protect these elements of its manufacturing process under state trade secret law.

Wyeth has never claimed the right to an injunction by extension of its patent rights. Instead, Wyeth contended, and established at trial, that the information Tankha placed at risk was not disclosed in any patent. Because federal patent law is not implicated by Tankha's malfeasance, the trial court properly issued an injunction which was adequate to protect Wyeth's state law-protected trade secret rights and which could be enforced with reasonable certainty.

As the Pennsylvania Superior Court and Supreme Court's affirmance of the trial court's injunction does no more than adequately protect Wyeth's state law created trade secret rights while offending neither the patent laws nor the Supremacy Clause of United States Constitution there is no basis for this Court to grant the Petition.

B. No Important Question Of Federal Law Is Raised By The Petition

1. The Trial Court's Injunction Does Not Disrupt the Balance Between Federal Patent and State Trade Secret Laws.

The production injunction prohibits Petitioner from engaging in the business of the manufacture of conjugated estrogens. The incidental consequence of that decree is that it necessarily restricts his ability to practice certain expired patents. That, by itself, does not raise a serious conflict with federal law. Petitioner's transparent

attempt to create an issue worthy of writ consideration from the issuance of the injunction rests on an imagined bright line between the enforcement of state trade secret law and the preemptive scope of federal patent law. His argument fails to acknowledge that each has been recognized by this Court to have its place in protecting legitimate property interests.

This Court has been sensitive to the states' ability to protect its citizens through the laws of unfair competition and trade secret even in areas that may impinge on federal patent rights. In order to accommodate the potential tension between federal and state law, this Court has, however, required that there be some additional compelling state law interest, whether arising from consumer confusion or, like here, a breach of trust or secrecy. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989). The protection of trade secrets and the prevention of industrial espionage have long been recognized by this Court as important state interests which require a level of accommodation under the Supremacy Clause.

As this Court stated in *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974):

> . . . state protection of trade secrets, as applied to both patentable and unpatentable subject matter, did not conflict with the federal patent laws. In both situations, state protection was not aimed exclusively at the promotion of invention itself, and the state restrictions on the use of unpatented ideas were limited to those necessary to promote goals outside the contemplation of the federal patent scheme. Both the law of unfair competition and state trade secret law have coexisted harmoniously with federal patent protection for almost 200 years, and Congress has given no indication that their operation is inconsistent with the operation of the federal patent laws.

Bonito Boats, 489 U.S. at 165-66 (describing the recognition of the balance between patent and trade secret laws struck in *Kewanee Oil*).

Nonetheless, Petitioner argues that the states' interest in protecting trade secrets is wholly subservient and must always give

way to patent law and policy. The Supremacy Clause, Petitioner further asserts, cannot accommodate any other result. There are few such absolutes in the law.[4] The potential conflict between federal patent law and state trade secret law suggested by Petitioner does not present an occasion for so rigid an approach. Such a black and white resolution of the tension between federal and state intellectual property interests has been directly rejected by this Court.

> Nothing in the patent law requires that States refrain from action to prevent industrial espionage. In addition to the increased costs for protection from burglary, wire-tapping, bribery, and other means used to misappropriate trade secrets, there is the inevitable cost to the basic decency of society when one firm steals from another. A most fundamental human right, that of privacy, is threatened when industrial espionage is condoned or is made profitable; the state interest in denying profit to such illegal ventures is unchallengeable.

Kewanee Oil Co., 416 U.S. at 487 (footnote omitted).

Moreover, this Court has repudiated the interpretation of its decisions that states are "completely disabled from offering any form of protection to articles or processes which fall within the broad scope of patentable subject matter". *Bonito Boats*, 489 U.S. at 154. There is simply no blanket patent law preemption of state law remedies for the protection of state recognized rights which might potentially implicate patentable subject matter. *Id.; cf. Analogic Corp. v. Data Translation, Inc.*, 371 Mass. 643; 358 N.E.2d 804 (1976) (no pre-emption by federal patent policy when state court enjoins defendants from making and selling an article which can be readily duplicated by reverse engineering but was the product of misappropriation).

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4 "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to "'stand by both concepts and to tolerate whatever tension there [is] between them.'" *Bonito Boats*, 489 U.S. at 166-67 (quoting *Silkwood v. Kerr-McGree Corp.*, 464 U.S. 238, 256 (1984)).

2. The Injunction Has No Far Reaching Impact On The Patent System

This Court has also been careful to note that the nature and extent of the state law protection of rights which may fall within the ambit of patent law is an important component of the preemption analysis. *Id.* at 155. In *Bonito Boats*, the Florida statute at issue substantially interfered with and contravened federal patent policy by reducing competitive incentive. In addition, the prospect of all fifty states establishing similar protections for preferred industries could have posed a "substantial threat to the patent system's ability to accomplish its mission of promoting progress in the useful arts". *Id.* at 161. The Florida statute at issue in *Bonito Boats* also threatened to erode one of the fundamental purposes of the Patent and Copyright Clauses of the Constitution, "to promote national uniformity in the realm of intellectual property". *Id.* at 162. The order of injunction at issue here poses no similar threat to the foundation of the patent system nor will it have the potential effect of undermining uniformity or federal patent policy. Such a fact driven, episodic remedy is simply not of constitutional dimension.

Finally, if Petitioner's contorted reasoning were to prevail, the patent law would have the insidious effect of virtually eliminating a state's ability to protect confidential technical information or to prevent industrial espionage. Any defendant in a matter involving trade secrets or confidential and proprietary technical information could simply search the patent office records for an expired patent related to some aspect of the disputed product or process. Citing to the patent, the defendant could claim an unfettered federal right to continue work on the misappropriated product or process, regardless of his or her contractual obligations or tortious conduct. This is neither the function of patent law nor of the Supremacy Clause and would be wholly inconsistent with this Court's holdings and rationale in *Kewanee Oil* and *Bonito Boats*.

The occasions for the issuance of an injunction like the one issued by the trial court here are few. As recognized in the Restatement (Third) of Unfair Competition, only "if there is a substantial risk of disclosure, an injunction...prohibiting participation in a particular project that presents a special risk of disclosure

may be appropriate." Restatement (Third) of Unfair Competition §44, cmt. c (1995); *see also, Monovis, Inc. v. Aquino*, 905 F. Supp. 1205 (W.D.N.Y. 1994) (production injunction appropriate where defendants could not be relied upon to not use or disclose plaintiffs' trade secrets); *Christopher M's Handpoured Fudge v. Hennon*, 699 A.2d 1272 (Pa. Super. 1997) (a "production injunction," preventing manufacture of a product, rather than a "use injunction," preventing an employee from using trade secrets, is warranted when a trade secret is inextricably connected to the manufacture of the product and the employee cannot be relied upon to not use the misappropriated technology.). It was precisely the extraordinary nature of Petitioner's actions as determined by the trial court that required the special relief granted. The trial court prohibited Petitioner from engaging in the production of conjugated estrogens only after making explicit findings that: (1) there was a "virtual impossibility" that Petitioner "could manufacture any conjugated estrogens product without using the secret, confidential and proprietary information obtained from Defendant Wyeth..." App. 28a, ¶15; (2) Petitioner "has expressly stated his intent to use his employer's exact process and has demonstrated his inability to proceed without using information he acquired during his employment." App. 33a, ¶32; and that (3) Petitioner's use of Wyeth's confidential information for his own personal advantage "is inevitable if [Petitioner] is permitted to engage, directly or indirectly, in the business of manufacturing any conjugated estrogens product..." App. 34a, ¶33.

Thus, the cumulative and damning evidence of Petitioner's deceit and attempted exploitation of Wyeth's trade secrets — while purportedly engaged in an endeavor based solely on expired patents — required that the scope of the injunction be sufficiently broad to effectively prevent him from trading on his knowledge of Wyeth's secret process. The trial and appellate courts' decisions were correct. The order at issue is not in conflict with the decisions of this, or any other court, and the injunction at issue is sui generis. For these and the other reasons presented, there is no question meriting review presented by the Petition.

CONCLUSION

The Petitioner presents no important conflict between federal patent law and a state court's recognized right to protect trade secrets pursuant to state trade secret law. The Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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